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Director

State of California—Health and Human Services Agency
California Department of Public Health



ARNOLD SCHWARZENEGGER
Governor

July 1, 2010

TO: INTERESTED PARTIES

SUBJECT: EXEMPTION TO HEALTH AND SAFETY CODE SECTION 124172
(MERCURY-CONTAINING VACCINES) FOR JAPANESE
ENCEPHALITIS VIRUS VACCINE INACTIVATED, 2010-2011

In 2004, to ensure that pregnant women and children younger than age three years have access to mercury-free vaccines, Governor Schwarzenegger signed AB 2943 (Pavley, Chapter 837, Statutes of 2004). Under the terms of AB 2943, since July 1, 2006, vaccines containing levels of mercury greater than specified limits cannot be administered to pregnant women and young children, except under certain circumstances.

While commonly used vaccines administered in the United States are available in mercury-free formulations for children and adolescents, the less frequently used Japanese encephalitis (JE) vaccine is not. JE, a mosquito-borne infection, is the leading cause of viral encephalitis (brain infection) in Asia and parts of Oceania. Since 2005 major outbreaks of JE have resulted in illness and death of thousands of persons in India and Nepal. Most persons with encephalitis caused by the JE virus either die or have residual neurologic disease. Unimmunized children in affected areas are at highest risk of JE, while infection during pregnancy may cause miscarriage. There is currently no treatment for JE. Each year, approximately 4,300 Californians (excluding military personnel) one year of age and older traveling for a month or longer in Asia or Oceania receive the JE vaccine in accordance with national medical and public health recommendations.

The U.S. Food and Drug Administration (FDA) has licensed only one vaccine against JE for use in children and adolescents in the United States. The formal name of the vaccine is Japanese Encephalitis Virus Vaccine Inactivated. Its trade name is JE-VAX®. It is manufactured by The Research Foundation for Microbial Diseases of Osaka University ("BIKEN®") and distributed in the United States by sanofi pasteur, Inc.

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In March 2009, FDA licensed the use of a second JE vaccine that is free of preservatives, including those containing mercury, for use in persons 17 years of age and older. This vaccine may be given to pregnant adults now and may be licensed for use in children and adolescents in the future.

Given the continuing absence of mercury-free JE vaccine for persons younger than 17 years of age and the risk of fatal disease or brain injury from JE, California Health and Human Services Agency Secretary Kimberly Belshé has exercised the authority provided by AB 2943, with concurrence from Governor Schwarzenegger, and granted an exemption from California Health and Safety Code section 124172 (a) for Japanese Encephalitis Virus Vaccine Inactivated in persons younger than 17 years of age for another year from July 1, 2010, to June 30, 2011. Previous 12-month exemptions for JE vaccine have been granted since July 2006 under the same authority for the same reasons. This exemption will allow the JE vaccine to be administered to children younger than three years old and pregnant women younger than 17 years old to protect against severe illness or death should they visit affected areas where they are at risk of infection.

Secretary Belshé and Governor Schwarzenegger have granted this exemption because of the health risk posed by JE virus to those residing or traveling in affected areas, and because there is no alternative vaccine for Californians seeking protection against JE.

Governor Schwarzenegger and Secretary Belshé remain deeply committed to implementing AB 2943 and ensuring that pregnant women and young children have access to mercury-free vaccines whenever possible.

If you have any questions, please contact the California Department of Public Health Immunization Branch at (510) 620-3737.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark B. Horton", with a stylized flourish at the end.

Mark B. Horton, MD, MSPH
Director